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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,637	10/27/2005	Min-Hyo Seo	1599-0293PUS1	9196
2292 7590 05/03/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
ROGERS, JAMES WILLIAM				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
05/03/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/554,637

Applicant(s)

SEO ET AL.

Examiner

JAMES W. ROGERS

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5 and 7-14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 3-5 and 7-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/05/2010 has been entered. Applicants amendments to the claims filed 02/09/2010 have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically claim 1 sets forth that a diol or polyol have between 3-12 hydroxyl groups, however diols by definition only have 2 hydroxyl groups. Furthermore claim 1 recites that n is the same number as hydroxyl groups that I contains yet n includes the value 2 which is not included in the range for number of hydroxyl groups in I (3-12).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-5 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al (WO 03/033593), cited previously in view of Sodergard (US 2004/0091573), cited previously in view of Li et al. (Polymer, 39, pp. 4421-4427 (1998)), cited previously.

Seo and LI are disclosed in the previous office action filed 07/17/2009. Seo does not disclose the specific polyol cores claimed nor multiarm polymers containing PLA.

Sodergard discloses multiarm polymers containing a core molecule including maltitol along with numerous other naturally occurring polyfunctional compounds of sugars and tri-saccharides and polymer arms containing units derived from lactic and glycolic acid. See [0006]-[0016]. Thus Sodergard is used primarily for the disclosure within that applicants claimed saccharide cores were well known at the time of the invention to be used as polyol cores in PLA multi-arm polymers. Since Sodergard discloses the use of PLA in the described multi-arm polymers one of ordinary skill in the art would have a high expectation of success in adding the PLA polymers of Seo to the star polymer of Sodergard. The reason to make such a modification to Seo is provided by the disclosure of Li who disclosed that multiarm polymers were well known to have advantageous properties for drug delivery compared to their linear counterparts, including enhanced structural stability and slower biodegradation rates. Since Seo relates to PLA polymers for solubilizing poorly soluble drugs it would have been obvious for one of ordinary skill in the art to make a multiarm PLA polymer in order to produce a drug delivery micelle composition that advantageously shows enhanced structural stability and a slower biodegradation rate. Thus the claimed invention would have been

prima facie obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Regarding new claim 14 that recites the branched polylactic acid derivative entraps drugs in micelles formed from the polymer, this intended use recitation is met by the combination above since the polymer by combination is the same it will also necessarily have the same properties as claimed such as its drug entrapping properties and its ability to form micelles. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

Response to Arguments

Applicant's arguments filed 02/09/2010 have been fully considered but they are not persuasive. Applicants assert that Sodergard is drawn to a gum base and as such is very far from their claimed technical field and the fields of Seo and Li. Thus applicants contend one of ordinary skill in the art would have not contemplated combining the art disclosed above in the 103 rejection.

The examiner respectfully disagrees, Firstly the references above are at least related in their teachings on the use of polylactic acid. Since Li teaches the advantages

of multi-arm PLA for drug delivery compared to its linear form one of ordinary skill in the art would have good reason to pursue known methods to make branched PLA polymers. One such method is described by Sodergard. Secondly Sodergard was only used as a secondary reference for its description on how to make PLA multiarm copolymers not for its description of how to use such polymers. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Lastly the examiner notes that applicant's claims are drawn to a multi-arm polymer, not a micelle drug containing formulation, the recitations within the claims on the polymers ability to carry drugs and form micelles are no more than intended use recitations that will not lead to a patentable difference from the cited art.

Claims 1,3,4,12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Journal of Polymer Science: Part A: Polymer Chemistry, Vol 39, 973-985 (2001)).

Lee discloses the synthesis of end group functionalized polylactides, the polylactides could be multi-armed via reaction with a core polyol such as pentaerythritol. See entire disclosure especially scheme 1 and figure 1. The functional groups on the end of the polymer included carboxylic acid groups produced from succinic anhydride. Lee while disclosing the same branched polylactide derivatives as

claimed by applicant is silent on a molecular weight for the macromolecule that is within applicants claimed range. However adjusting the molecular weight in this polymer is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal molecular weight for the branched polylactide to achieve the desired results. For instance, the introduction section of Lee describes how PLA may be used in biomedical applications where it may be necessary to adjust the degradation rate of the polymer by adjusting several parameters including the molecular weight of the polymer. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of molecular weight would have been obvious at the time of applicant's invention. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33; *In re Russell*, 169 USPQ 426. Regarding claim 12 Lee describes that PLA has been widely used for drug delivery, thus the use of the branched PLA derivatives disclosed in Lee for drug delivery compositions would have been obvious. Claim 14 sets forth an intended use type of recitation where the branched PLA derivatives are capable of forming micelles and solubilizing poorly water soluble drugs. Since the branched PLA derivatives of Lee are within applicants claims scope it will be capable of forming a micelle and solubilizing poorly water soluble drugs.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618